

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

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MERCK SHARP & DOHME CORP.,  
CUBIST PHARMACEUTICALS LLC,  
OPTIMER PHARMACEUTICALS LLC,  
MSD INVESTMENT HOLDINGS  
(IRELAND), and MSD INTERNATIONAL  
GMBH,

Plaintiffs,

v.

ACTAVIS LABORATORIES FL, INC.,

Defendants.

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**OPINION AND ORDER**

Civ. No. 15-6541 (WHW)(CLW)

**Walls, Senior District Judge**

Plaintiffs Merck Sharp & Dohme Corp., Cubist Pharmaceuticals LLC, Optimer Pharmaceuticals LLC, MSD Investment Holdings (Ireland), and MSD International GmbH (collectively “Plaintiffs” or “Merck”) object to and appeal, under Local Civil Rule 72.1(c)(1)(A) and Federal Rule of Civil Procedure Rule 72(a), from the Hon. Cathy L. Waldor’s May 5, 2017 Order granting Defendant Actavis Laboratories FL, Inc. (“Actavis”) leave to amend its patent invalidity contentions. ECF No. 101. The Court decides this motion without oral argument under Fed. R. Civ. P. 78. Magistrate Judge Waldor’s order is affirmed.

**BACKGROUND**

This case arises under the Hatch-Waxman Act. Compl., ECF No. 1. Plaintiffs allege that the filing of Actavis’ ANDA No. 208443—seeking FDA approval to engage in the marketing and sale of generic versions of Plaintiffs’ Difucid® (fidaxomicin) tablets—infringes U.S. Patent Nos. 7,906,489, 8,586,551, 7,378,508, 7,863,249, and 8,859,510. ECF No. 105 at 2. Defendant

Actavis asserts that each of the identified patents is invalid and/or unenforceable. The asserted claims of the '489 and '551 patents (the "compound patents") all cover the allegedly novel chemical compound known as fidaxomicin. *Id.* The asserted claims of the '508, '249, and '510 patents (the "polymorph patents") all cover the same allegedly novel crystal form (called a "polymorph") of fidaxomicin. *Id.*

Plaintiffs filed suit on August 31, 2015, ECF No. 1, a little over a month after Actavis submitted its Abbreviated New Drug Application ("ANDA") to the FDA, and notified Plaintiffs through its Paragraph IV Certification that it sought to produce a generic version of Difucid®. *Id.* ¶ 52. Defendant's Paragraph IV certification informed Plaintiffs of Actavis' position that Merck's "Orange Book" patents were either invalid or that Actavis' proposed generic product did not infringe Plaintiffs' patents. *Id.* ¶ 54.

In accordance with the Court's Scheduling Order, Actavis served its Local Patent Rule 3.3 invalidity contentions on Defendants on April 5, 2016. ECF No. 105 at 2. Plaintiffs responded to Defendant's initial invalidity contentions in May 2016. *Id.* at 3. Following the filing of the first invalidity contentions and Plaintiffs' response, the parties began discovery, which included the production of over 3 million pages of documents as well as interrogatory requests and responses. *Id.* at 4. On October 17, 2016, Actavis expanded its invalidity theories with amended invalidity contentions, which Plaintiffs did not oppose. ECF No. 70.

In October 2016, Actavis served a subpoena on the named inventor of a crystal of fidaxomicin, Dr. Youe-Kong Shue, in order to evaluate whether the fidaxomicin crystal described in a report known as the Scripps Reports depicted the same crystal disclosed in Plaintiffs' '462 patent prior art publication. *Id.* at 5. Apparently, when Plaintiffs applied for the polymorph patents, Dr. Shue submitted a declaration to the Patent Office stating that the crystal

disclosed in Plaintiffs' '462 publication was not the same as the claimed crystal in the polymorph patents. However, at his December 20, 2016 deposition, Dr. Shue confirmed that the data from the Scripps Report was from the very crystal contained in the '462 prior art reference. *Id.*; Shue Dep., Ex. 7, at 249–255).

On January 17, 2017, only three days before the original deadline for the close of fact discovery, Defendant disclosed to Plaintiffs its proposed second amended invalidity contentions.<sup>1</sup> ECF No. 105 at 5. As is relevant here, Actavis proposed “adding one paragraph explaining how the Scripps Report supports Actavis’s defense that the “polymorph patents” are invalid based on the ‘462 publication,” and a citation to a prior art publication (the “’990 publication”), which Actavis claims “contains the exact same pertinent information as the ‘462 prior art publication. *Id.* Actavis contends that the addition of the ‘990 publication “does not add or expand any invalidity theory,” but serves as insurance if Plaintiffs decide to eliminate the ‘462 publication as prior art. *Id.*

Plaintiffs objected to Defendant’s proposed invalidity amendments, arguing that Actavis’s request to add the Scripps Report and the ‘990 publication to its invalidity contentions was unjustifiably untimely, without good cause, and prejudicial, and thus it failed to meet the requirements of Local Patent Rule 3.7. ECF No. 101-1 at 4. Plaintiffs argue that Actavis’s amendments are untimely and lacked diligence because both the Scripps Report and the ‘990 publication were available to Actavis from the outset of the litigation if not sooner. *Id.* Consequently, Plaintiffs strongly disagree with Actavis’s characterization that its proposed amendments constitute “new information” uncovered during depositions. *Id.*

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<sup>1</sup> On February 1, 2017 parties stipulated to amend the case schedule because of a 30-month stay ending November 27, 2018 due to the FDA granting Dificid® “New Chemical Entity” market exclusivity. The amended deadline for fact discovery was February 28, 2017.

## NOT FOR PUBLICATION

On March 16, 2017 the parties submitted a joint letter brief on the dispute to Magistrate Judge Waldor. On May 5, 2017, having received and considered each party's position, Magistrate Judge Waldor issued an Order granting Actavis' motion to amend its invalidity contentions. The Order reads:

Actavis' informal Motion to Amend its invalidity contentions to include the '990 and '462 publications is granted as dictated by L. Pat. R. 3.7. The Court finds that the application is timely; a sufficient showing of good cause has been made; and that the plaintiff will not be prejudiced by the amendments. The projected trial date is some twelve months out, if time is needed for the experts to consider the amendments, the parties shall meet and confer and agree upon an extension schedule. Leave is granted to amend invalidity contentions as appears on pages 26, 38, 57, 65, 67, and 68 of Defendant Actavis' Second Amended Invalidity Contentions.

ECF No. 100.

On May 19, 2017, Plaintiffs filed this appeal of Magistrate Waldor's May 5, 2017 Order granting Defendant's motion to amend its invalidity contentions. ECF No. 101. Plaintiffs argue that the Order "is contrary to law and is clearly erroneous" because it focused only on prejudice, effectively reading out the Local Patent Rules' requirement that a motion to amend invalidity contentions be timely and for good cause. ECF No. 101-1 at 1. Plaintiffs also request that Actavis' January 20, 2017 interrogatory responses be stricken to the extent they cite to and discuss the Scripps Report and the '990 publication. *Id.* at 12-13. Actavis opposes Plaintiffs' appeal. ECF No. 106.

### STANDARD OF REVIEW

A magistrate judge may hear and determine any non-dispositive pretrial matter pending before a district court, including motions to amend pleadings. *Miller v. Beneficial Management Corp.*, 844 F. Supp. 990, 997-98 (D.N.J. 1993); 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a). A district court may only reconsider a magistrate's ruling on a non-dispositive pretrial matter if it

is “clearly erroneous or contrary to law.” *United Steelworkers of America v. New Jersey Zinc*, 828 F.2d 1001, 1005 (3d Cir. 1987); 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); L. Civ. R. 72.1(c)(1)(A). A decision is “contrary to law” if the magistrate judge has misinterpreted or misapplied applicable law. *Gunter v. Ridgewood Energy Corp.*, 32 F. Supp. 2d 162, 164 (D.N.J. 1998). A decision is “clearly erroneous” if the reviewing court, when looking at the evidence that was presented to the magistrate judge, is left with the “definite and firm conviction that a mistake has been committed.” *Richardson v. Allied Interstate, Inc.*, 2010 WL 3404978, at \*3 (D.N.J. Aug. 26, 2010) (quoting *Dome Petroleum Ltd. v. Employers Mut. Liab. Ins. Co.*, 131 F.R.D. 63, 65 (D.N.J. 1990)). Absent a finding that the decision was clearly erroneous or contrary to law, the reviewing court may not reverse a magistrate judge’s decision, even if the reviewing court might have decided the matter differently. *Cardona v. General Motors Corp.*, 942 F. Supp. 968, 971 (D.N.J. 1996).

## DISCUSSION

Under Local Patent Rule 3.7, leave to amend invalidity disclosures may be granted “by order of the Court upon a timely application and showing of good cause.” L. Pat. R. 3.7. A motion to amend invalidity contentions is only granted if: “(1) the moving party makes a timely application to the court; (2) there is good cause for the amendment; and (3) there is no undue prejudice to the adverse party.” *AstraZeneca AB v. Hanmi, USA, Inc.*, No. 11–760, 2013 WL 264609, at \*1 (D.N.J. Jan. 23, 2013). Unlike the liberal standard for amending pleadings, “the philosophy behind amending claim charts is decidedly conservative, and designed to prevent the ‘shifting sands’ approach to claim construction.” *King Pharms., Inc. v. Sandoz, Inc.*, No. 08–

5974, 2010 WL 2015258, at \*4 (D.N.J. May 20, 2010) (citing *Atmel Corp. v. Info. Storage Devices, Inc.*, No. 95–1987, 1998 WL 775115, at \*2 (N.D. Cal. Nov. 5, 1998)).

After a review of the record, the Court notes that there arguably are several reasons to deny Actavis' request to amend its invalidity contentions in this matter. In fact, if presented with the parties' arguments in the first instance, the Court may have been inclined to deny the request to amend. However, the standard of review here is not whether this Court disagrees with Magistrate Judge Waldor's ultimate decision; it is whether the decision is clearly erroneous or contrary to law. *See Jazz Pharms., Inc. v. Roxane Labs., Inc.*, No. 10–6108, 2013 WL 785067, at \*4 (D.N.J. Feb. 28, 2013) ("In short, mere disagreement with the judicial finding of a Magistrate Judge does not meet the 'clear error' standard required for reversal."); *see also Novartis Pharm., Corp. v. Wockhardt USA LLC*, No. CIV.A. 12-3967 SDW, 2013 WL 4732296, at \*2 (D.N.J. Sept. 3, 2013). A careful examination of the facts and arguments presented reveals that Magistrate Judge Waldor's decision is neither clearly erroneous nor contrary to law.

Plaintiffs' appeal focuses on the requirement of good cause.<sup>2</sup> To establish good cause, parties must "proceed with diligence in amending [their] contentions when new information comes to light in the course of discovery." *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006). The moving party has the burden of demonstrating its diligence. *Id.* Furthermore, the moving party must show that it was both diligent throughout

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<sup>2</sup> Plaintiffs argue in a footnote that the Order is "also clearly erroneous in concluding that there would be no prejudice to Plaintiffs" because Defendant's invalidity claim related to the '462 publication is vague and the '990 publication has a different priority date than the '462 publication, potentially putting it in a different category of prior art. ECF No. 101-1 at 11-12 n.4. An adverse party does not suffer undue prejudice merely because it is "operating under [the] original non-infringement contentions" and made "develop[ments] [in] strategies based on these contentions." *Hanmi*, 2013 WL 264609, at \*2. Furthermore, an adverse party is not prejudiced if an amendment results in "minor adjustment[s]" to the case schedule. *Id.*; *see also Novartis*, 2013 WL 4732296, at \*4. Magistrate Judge Waldor found no prejudice to Plaintiffs based on the late 2018 projected trial date, which makes it easy to adjust case deadlines (if necessary) to accommodate the amended contentions. The Court agrees, so Magistrate Judge Waldor's conclusion that there is no prejudice to Plaintiffs as a result of Defendant's amended invalidity contentions is not clearly erroneous.

discovery and in “discovering the basis for the proposed amendment.” *West v. Jewelry Innovations, Inc.*, No. 07–1812, 2008 WL 4532558, at \*2 (N.D. Cal. Oct. 8, 2008). In determining whether good cause exists, courts have also considered such other factors as (1) the reason for the delay, including whether it was within the reasonable control of the party responsible for it; (2) the importance of what is to be excluded; (3) the danger of unfair prejudice; and (4) the availability of a continuance and the potential impact of a delay on judicial proceedings. *See Oy Ajat, Ltd. v. Vatech Am., Inc.*, 2012 WL 1067900, at \*20–21 (D.N.J. Mar. 29, 2012) (collecting cases).

Plaintiffs argue that Magistrate Judge Waldor either failed to find good cause or that any finding of good cause was clearly erroneous. ECF No. 101-1 at 10–13. Plaintiffs’ first contention is essentially that Magistrate Judge Waldor did not apply the correct legal standard because her “Order [] is silent on the issue of diligence,” a necessary element of good cause. *Id.* at 11. Plaintiffs further note that Magistrate Judge Waldor’s Order only provides a factual analysis for her finding that there would be no prejudice to Plaintiffs. *Id.* But these arguments do not support the conclusion that Magistrate Judge Waldor applied the wrong legal standard to Defendant’s motion. The Order specifically states that Defendant’s application to amend its invalidity contentions “is timely; a sufficient showing of good cause has been made; and that the plaintiff will not be prejudiced by the amendments.” These conclusions address all of the necessary elements the moving party must prove for a court to grant a motion to amend its invalidity contentions. *See Hanmi*, 2013 WL 264609, at \*1. Despite Magistrate Waldor’s failure to specifically mention diligence in her finding of good cause, there is no support for Plaintiffs’ argument that she failed to apply the correct standard to Defendant’s motion.

Plaintiffs next argue that Magistrate Judge Waldor’s Order should be overturned because

“to the extent a finding of diligence was made . . . that finding was clearly erroneous. ECF No. 101-1 at 12. At bottom, Plaintiffs’ argument as to both the Scripps Report and the ‘990 publication is that Actavis knew or should have known about the documents long before the litigation began, making it impossible for them to now establish that their proposed amended invalidity contentions meet the diligence standard essential to good cause. ECF No. 101-1 at 6–13. Actavis vociferously disputes Plaintiffs’ assertions as to the availability of these documents, arguing that the relevant portions were only first disclosed confidentially, under the protective order in this case, and that the importance of the now-cited portions could not be established except through Dr. Shue’s expert testimony and in consultation with expert crystallographers timely consulted by Actavis. ECF No. 105 at 11–16. Finally, Defendant asserts that the addition of the ‘990 publication is only necessary due to an ongoing dispute with Plaintiffs regarding whether they intend to “sear around” the ‘462 publication in an attempt to eliminate it as prior art. *Id.* at 15.

Local Patent Rule 3.7 provides a nonexhaustive list of “circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause.” Though the circumstances offered by Actavis do not squarely<sup>3</sup> meet one of the enumerated reasons to allow amendments to invalidity contentions, it was not clearly erroneous to allow Actavis to amend its invalidity contentions based on the diligent uncovering of new information through deposition discovery and consultation with hired experts. *See Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd.*, No. CIV.A. 11-3962 MLC, 2013 WL 3336859, at \*4 (D.N.J. July 2, 2013) (“That pieces of the puzzle might have been revealed at earlier times does not mean that a complete picture was likewise available.”); *Positive Techs., Inc. v. Sony Elecs., Inc.*, No. C 11-2226 SI, 2013 WL

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<sup>3</sup> Local Patent Rule 3.7(b) supports a finding of good cause in cases of “recent discovery of material prior art despite earlier diligent search.” These circumstances meet the spirit of this example if not the letter.



322556, at \*3 (N.D. Cal. Jan. 28, 2013) (granting defendant's motion to amend its invalidity contentions six months after plaintiff's filed its Markman brief because defendant's "multi-tier review" of previously disclosed information showed sufficient diligence); *see also Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, No. CIV. 12-3289 PGS LHG, 2014 WL 997532, at \*7 (D.N.J. Jan. 6, 2014), *aff'd*, No. CIV.A. 12-3289 PGS, 2014 WL 1494592 (D.N.J. Apr. 16, 2014) (denying defendant's motion to amend invalidity contentions, but recognizing that "[t]he [Local Patent] Rules clearly contemplate a situation in which discovery or further investigation by a party, including by the party expert, may lead to the need to expand the invalidity contentions.")). In this case, a finding of good cause is further supported by Defendant's argument that it believed a declaration submitted by Dr. Shue to the patent office stating that the claimed crystal polymorph was distinct from the crystal disclosed in the '462 publication might be contradicted by statements made in his deposition when he was presented with previously confidential portions of the Scripps Report. When Dr. Shue confirmed Defendant's suspicion, Actavis proposed the amended contentions within three weeks during the December holidays.

Finally, it was not clearly erroneous for Magistrate Judge Waldor to allow Defendant to amend its invalidity contentions to include the '990 publication. Defendant only seeks to add the '990 publication to prevent Plaintiffs from "swearing around" a previously disclosed prior art (the '462 publication) after discussions between the parties to avoid the problem fell through. ECF No. 105 at 16–17. Because the '990 publication is not materially different from previously disclosed prior art, and the new information provided by Dr. Shue regarding the Scripps Report might prompt Plaintiffs to "swear around" the '462 publication, Magistrate Judge Waldor's finding of good cause with respect to the '990 publication was not clearly erroneous. *Kilopass Tech. Inc. v. Sidense Corp.*, No. C 10-02066 SI, 2012 WL 1901198, at \*3 (N.D. Cal. May 24,

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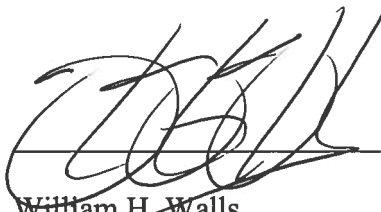
2012) (finding good cause to amend patent invalidity contentions after the close of fact discovery where the party's expert identified potential new defenses and the contentions did not "substantially depart" from the original contentions).

### CONCLUSION AND ORDER

Magistrate Judge Waldor's May 5, 2017 Order granting Actavis' motion to amend its invalidity contentions was not clearly erroneous or contrary to law. It is hereby ORDERED that Plaintiffs' objection to, and appeal of, the May 5, 2017 Order, ECF No. 101, is denied, and it is further ORDERED that Plaintiffs' request that Actavis' January 20, 2017 interrogatory responses be stricken to the extent they cite to and discuss the Scripps Report and the '990 publication is denied.

DATE:

10 July 2017



William H. Walls  
Senior United States District Court Judge